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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,333	07/03/2003	R. Rogers Yocum	BGI-154B	5952

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LAHIVE & COCKFIELD
28 STATE STREET
BOSTON, MA 02109

EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/614,333	Applicant(s) YOCUM ET AL.	
	Examiner Christian L. Fronda	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claim(s) 1-15, drawn to a process for enhanced production of pantothenate comprising culturing a microorganism having a deregulated methylenetetrahydrofolate (MTF) biosynthetic pathway, classified in class 435, subclass 106.
 - II. Claim(s) 16-22, drawn to a process for enhanced production of pantothenate comprising culturing a microorganism having a deregulated pantothenate biosynthetic pathway, a deregulated isoleucine-valine (ilv) biosynthetic pathway, and a deregulated methylenetetrahydrofolate (MTF) biosynthetic pathway, classified in class 435, subclass 106.
 - III. Claim(s) 29, drawn to a process for producing pantothenate comprising culturing a microorganism having a deregulated pantothenate biosynthetic pathway under excess serine, classified in class 435, subclass 106.
 - IV. Claim(s) 34, 35, drawn to a composition comprising pantothenate, classified in class 562, subclass 571.
 - V. Claim(s) 36-41, drawn to a recombinant microorganism for the enhanced production of pantothenate, said microorganism having a deregulated pantothenate biosynthetic pathway, and a deregulated methylenetetrahydrofolate biosynthetic pathway, classified in class 435, subclass 252.3.
 - VI. Claim(s) 42, 43, drawn to a process for producing pantothenate comprising culturing a recombinant microorganism having a deregulated panB gene, a deregulated panD gene, and at least one deregulated isoleucine-valine (ilv) biosynthetic enzyme-encoding gene, classified in class 435, subclass 106.
 - VII. Claim(s) 44, drawn to a process for producing pantothenate comprising culturing a microorganism having a deregulated panB gene, a deregulated panD gene under conditions of excess serine, classified in class 435, subclass 106.

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- VIII. Claim(s) 45, drawn to a process for producing pantothenate comprising culturing a recombinant microorganism having a deregulated panB gene, a deregulated panD gene, and a deregulated methylenetetrahydrofolate (MTF) biosynthetic pathway under conditions of excess valine, classified in class 435, subclass 106.
 - IX. Claim(s) 46, drawn to a process for producing pantothenate comprising culturing a recombinant microorganism having a deregulated panB gene, a deregulated panD gene, and a deregulated glyA gene under conditions of excess valine, classified in class 435, subclass 106.
 - X. Claim(s) 47, drawn to a process for producing pantothenate comprising culturing a recombinant microorganism having a deregulated panB gene, a deregulated panD gene, and a mutated, deleted, or disrupted purR gene under conditions of excess valine, classified in class 435, subclass 106.
 - XI. Claim(s) 48, drawn to a process for producing pantothenate comprising culturing a recombinant microorganism having a deregulated panB gene, a deregulated panD gene, and a deregulated serA gene under conditions of excess valine, classified in class 435, subclass 106.
 - XII. Claim(s) 49, drawn to a process for producing pantothenate comprising culturing a recombinant microorganism having a deregulated panB gene, a deregulated panD gene, a deregulated serA gene, and a deregulated glyA gene under conditions of excess valine, classified in class 435, subclass 106.
2. The inventions are distinct, each from the other because of the following reasons:
- Inventions of Groups IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Each of the products of Groups V and VI are different and independent products and require different literature searches.
- Inventions of Groups I-III and VI-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The processes of Groups I-III and VI-XII are patentably distinct and independent because each process requires different process steps, reagents, and parameters.

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Group V and each of Groups I-III and VI-XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product such as using the recombinant microorganism in a recombinant protein expression process to express and produce recombinant proteins.

Each of Groups I-III and VI-XII and Group IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process such as using chemical synthesis methods to make the pantothenate composition of Group IV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and classification, restriction for examination purposes as indicated is proper.

3. Claims 23-28 link inventions of Groups I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claim 23-28 and 30-33.

Claims 30-33 link inventions of Groups I-III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 30-33.

Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory

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double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. A telephone call was made to Debra Milasincic on 06/01/2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

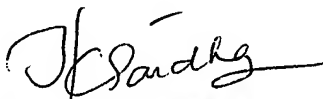
6. Any inquiry concerning this communication or earlier communications from the examiner

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should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF


TEKCHAND SAIDHA
PRIMARY EXAMINER